

**REMARKS**

Claims 1, 6, 9, 14-22 and 27-30 are pending, with Claims 3-5, 7-8 and 10-13 cancelled, with Claims 21-22 withdrawn as being directed to a nonelected invention, with Claims 23-26 not entered, and with Claims 27-30 currently added. Accordingly, Claims 1, 6, 9, 14-20, and 27-30 are under active consideration.

Claims 23-26 were indicated as "not entered" in the Advisory Action mailed July 6, 2007. Accordingly, by the present amendment, duplicates of Claims 23-26 (not entered) are added as Claims 27-30 (new). Support for new Claims 27-30 can be found throughout the specification and the claims as originally filed, at e.g., specification page 22, line 16 to page 23, line 5. Applicants request entry of new Claims 27-30, or alternatively, entry of Claims 23-26 and cancellation of Claims 27-30. No new matter has been added by the present amendment. A listing of the claims with appropriate status identifier begins on page 2.

With respect to all amendments and cancelled claims, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover, have not acquiesced to any rejections or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Applicants respectfully request rejoinder of Claims 21-22 in the event that Claims 1 and/or 14 are allowed, from which Claims 21-22 depend, respectively. Applicants have carefully considered the points raised in the Office Action and believe that the Examiner's concerns have been addressed as described herein, thereby placing this case into condition for allowance.

*Rejections under 35 U.S.C. §103*

The rejection of Claims 1-20 under 35 U.S.C. §103(a) as allegedly being unpatentable over Young *et al.* (U.S. Pat. No. 5,677,279; hereinafter "Young") in further view of Brain *et al.* (U.S. Pat. No. 7,045,533; hereinafter "Brain") and Jorgensen *et al.* (U.S. Pat. No. 4,370,317; hereinafter "Jorgensen"), is respectfully traversed.

The Supreme Court has addressed the issue of obviousness in *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007). The Court stated that the Graham factors (*Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966)), still control an obviousness inquiry. Those factors are: 1) "the scope and content of the prior art"; 2) the "differences between the prior art and the claims"; 3) "the level of ordinary skill in the pertinent art"; and 4) objective evidence of nonobviousness. *KSR*, *id.* at 1734 (quoting *Graham*, *id.* at 17-18). While the *KSR* Court rejected a rigid application of the teaching, suggestion, or motivation ("TSM") test in an obviousness inquiry, the Court acknowledged the importance of identifying "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does" in an obviousness determination. *KSR*, *id.* at 1731. In this regard, "[r]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR*, *id.* at 1741 (quoting *In re Kahn* 441 F.3d 977, 988 (Fed. Cir. 2006) (*emphasis added*). Further, as the *KSR* Court recognized, "[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp." *KSR*, *id.* at 1732. In such circumstances, "the fact that a combination was obvious to try might show that it was obvious under § 103." *Id.* However, the prior art must still suggest a predictable outcome to establish a *prima facie* case of obviousness (*emphasis added*). See, e.g., *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.* 492 F.3d 1350, 83 U.S.P.Q.2d 1169 (Fed. Cir. 2007).

Independent Claim 1 as currently amended is directed to a method of treating pancreatitis in a mammalian subject by administration of an effective amount of an amylin or an amylin analog, wherein the amylin analog has amylin agonist activity. Independent Claim 14 as currently amended is directed to improving a method of treatment for pancreatitis of a mammalian subject by administration of an amylin or an amylin analog in addition to an agent or regimen used to treat pancreatitis, wherein the amylin analog has amylin agonist activity. The claimed invention relies on Applicants' discovery that administration of a compound with amylin activity can be used to treat pancreatitis, an inflammatory process in which pancreatic enzymes

are released into the pancreas and surrounding tissues. As described and demonstrated in the specification, administration of a compound with amylin agonist activity treats pancreatitis by, e.g., reducing pancreatic enzyme secretion (e.g., specification as filed, paragraph [0021]).

In contrast, Young merely describes the use of an amylin or amylin agonist for treating or preventing pain. Thus, Applicants disagree with the Examiner's assertion (Office Action, page 3, line 9) that "Young teaches a method of relieving the pain and/or treating painful inflammation disorders ... (emphasis added)." The Examiner has provided no evidence that Young contemplates treatment of the underlying pathology in any painful inflammation disorder, let alone pancreatitis. Indeed, even while Young discloses (Col. 4, lines 63-65) that "[p]ain is also present in most inflammatory conditions, and is associated with tumor-related diseases or their treatment," Young nonetheless contemplates treatment of pain, not treatment of any underlying disease and specifically not pancreatitis. Accordingly, Young does not teach or suggest the use of an amylin or an amylin analog having amylin agonist activity for treating pancreatitis as required by the current claims.

In order to cure the deficiency of Young, the Examiner asserts (Office Action, page 3, lines 17-18) that "Brain et al. beneficially teach that pancreatitis is a very painful inflammation condition and/or inflammation disorder ... ." Applicants respectfully submit that the Examiner has provided no evidence that Brain contemplates treatment of pancreatitis with an amylin or an amylin analog having amylin agonist activity.

The Examiner further asserts (Office Action, page, lines 19-21) that "Jorgensen et al. beneficially teach that pancreatin treats pancreatitis ..." Applicants respectfully submit that the Examiner has provided no evidence that Jorgensen contemplates treatment of pancreatitis with an amylin or an amylin analog having amylin agonist activity.

In view of Young and Brain, the Examiner alleges (Office Action, page 4, lines 1-10) that

[i]t would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have administered the same amylin analog as the claimed invention's amylin analog of 25,28,29 Pro-h-amylin and an analgesic to treat the painful inflammation disorder of pancreatitis in a mammalian subject

because Young teaches that the amylin analog of 25,28,29 pro-h-amylin and an analgesic treats painful inflammation disorders and Brain teaches that pancreatitis is a painful inflammation disorder. Thus, when the same amylin analog as the claimed invention's analog of 25,28,29 pro-h-amylin in combination with an analgesic are administered to a mammalian subject for treating painful inflammation disorders, it would intrinsically treat the painful inflammation disorder of pancreatitis (*emphasis added*).

The Examiner further alleges (Office Action, page 4, lines 10-16) that

it would have been obvious to modify Young's administration's method of administering the same amylin analog as the claimed inventions amylin analog of 25,28,29 pro-h-amylin in combination with an analgesic to include the teaching of Jorgensen which states a pancreatic enzyme such as pancreatin is well known in the art for treating pancreatitis ... (*emphasis added*)"

Initially, Applicants note that the Examiner's reliance (Office Action, page 4, lines 1-7) in the current rejection on an "analgesic" (see emphases *supra*) administered with the amylin or amylin analog does not form an element of either independent Claims 1 or 14. Accordingly, for at least this reason, Applicants respectfully submit that the current rejection is irrelevant with respect to Claims 1, 6, 9, 14-17, 19-20, and 27-30, which claims do not require an analgesic element, and Applicants respectfully request allowance of at least Claims 1, 6, 9, 14-17, 19-20, and 27-30. Alternatively, in the event that a subsequent Office Action is issued, Applicants respectfully request that such Office Action not be made final because the claims are not currently amended. See MPEP § 706.07(a).

Regarding the combination of references Young and/or Brain and/or Jorgensen, there is no reasonable expectation of success in combining the references so as to arrive at the presently claimed methods. Therefore, the references do not provide a predictable outcome for treating pancreatitis, as required by the law. See *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, (*id.*) Although Brain may allude to pancreatitis as a painful condition, and Young and Brain may disclose general analgesic properties, there is no teaching, suggestion or indeed any rational underpinning for the proposition that analgesic compounds can actually treat pancreatitis. See *KSR*, (*id.* at 1741). In particular, the Examiner has provided no objective reasoning with rational underpinning why the treatment of pain, as disclosed e.g. by Young and/or Brain, would be

expected to treat pancreatitis. Furthermore, the Examiner has provided no objective reasoning with rational underpinning as to why one skilled in the art when confronted with the universe of all possible analgesic compounds would be directed to specifically select an amylin or an amylin analog having amylin agonist activity.

Indeed, in construing the claims, the Examiner has apparently equated treatment of pancreatitis with providing analgesia. This construction of the claims by the Examiner is contrary to the doctrine of claim interpretation. The doctrine of claim differentiation is "based on the common sense notion that different words or phrases used in separate claims are presumed to indicate that the claims have different meanings and scope." *Karlin Tech. Inc. v. Surgical Dynamics, Inc.*, 177 F.2d 968, 971-72 (Fed. Cir. 1999). Claim 3 as originally filed, which ultimately depends from Claim 1, provides that the method "simultaneously treats pancreatitis and the pain associated therewith." See also specification as filed, paragraph [0048]. If, as under the Examiner's apparent claim construction, providing analgesia is synonymous with treating pancreatitis, then Claim 3 is redundant. In accordance with the doctrine of claim differentiation, the separation of treating pancreatitis and alleviating pain associated with pancreatitis in both the claims and the specification require a claim construction different from that used by the Examiner to support the present rejection.

Furthermore, Applicants respectfully submit that in any event the association between pain and pancreatitis is not absolute. Indeed, as disclosed in the specification as filed (e.g., end of paragraph [0008]) "[w]hile pain is also often seen in chronic pancreatitis, the pain may be continuous or intermittent or absent (*emphasis added*)." The Federal Circuit has held that the "fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993); emphasis in original. "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the references, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson* 169 F.3d 743, 745

(Fed. Cir. 1999); emphasis added. Accordingly, although pancreatitis can be a painful disorder, not all patients with pain necessarily have pancreatitis, and not all patients with pancreatitis necessarily have pain. Thus, a reference which teaches treating pain with an amylin or amylin agonist does not necessarily teach treating pancreatitis as claimed. Thus, treating pancreatitis cannot be recognized by one skilled in the art as inherently taught in Young in combination with Brain and/or Jorgensen.

Indeed, none of the cited references, either alone or combined, teach that an amylin or an amylin analog having amylin agonist activity can treat pancreatitis, by e.g. reducing the level of pancreatic enzyme secretion or activity. Indeed, it was Applicants' discovery that an amylin or an amylin analog having amylin agonist activity could be used to treat pancreatitis. Accordingly, alone or combined, the cited references do not teach or suggest with any rational underpinning or predictable outcome that an amylin or an amylin analog having amylin agonist activity can be used to treat pancreatitis. Thus, the cited references do not support a *prima facie* case of obviousness. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §103.

**CONCLUSION**

Applicants believe that all issues raised in the Office Action have been properly addressed in this response. Accordingly, reconsideration and allowance of the pending claims is respectfully requested. If the Examiner feels that a telephone interview would serve to facilitate resolution of any outstanding issues, the examiner is encouraged to contact Applicants' representative at the telephone number below.

No additional fees are believed due for this submission. However, if a fee is due, the Commissioner is hereby authorized to charge payment of any fees associated with this communication, to Applicant's Deposit Account No. 010535 referencing Docket No. 0101-UTL-0. Additionally, the Commissioner is hereby authorized to charge payment or credit overpayment of any fees during the pendency of this application to Applicant's Deposit Account No. 010535.

Date: 5 May, 2008

Respectfully submitted,

AMYLIN PHARMACEUTICALS, INC.

A handwritten signature in black ink, reading "Steven C. Koerber", written over a horizontal line.

Steven C. Koerber  
Reg. No. 54,233

Amylin Pharmaceuticals, Inc.  
9360 Towne Centre Drive  
San Diego, California 92121  
Phone (858) 754-4121  
Facsimile (858) 552-1936